REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Status of the claims

Claims 1, 3-5, 7, and 14-18 were pending in the subject application. With this Response, claim 1, 5, 7, 14 and 15 have been amended; claims 3 and 16 have been canceled without prejudice to future prosecution. No claims have been newly added.

Hence, upon entry of this paper, claims 1, 4, 5, 7, and 14, 15, 17 and 18 will be pending in the subject application and under active consideration.

Statement of the substance of an interview

Applicant thanks the Examiner for agreeing—in a telephonic interview on 10 July 2009—to issue a "new" Office Action correcting certain omissions in the Office Action dated 14 April 2009.

Claim amendments

Claim 1 has been amended to a "homogenous" matrix comprising a pharmaceutically active agent and a fat-wax matrix material or "particles" of polymeric material selected from hydrophilic polymer and inert plastic. Support for "homogenous" is evident from at least Example 1, teaching that a formulations "was blended and granulated"; and support for "particles" may be found at least at paragraph "20" of the application as filed. Furthermore, the pharmaceutically active agent has been defined as one that is "absorbed systemically in the gastrointestinal (GI) tract; is not absorbed through the oral mucosa to a substantial extent; and is absorbed solely in the upper GI tract." Support for these amendments may be found, at least, in original claim 1 and paragraph "09" of the application as filed.

Claim rejections under 35 U.S.C. § 112

35 U.S.C. § 112, first paragraph

Claims 1, 3-5, 7 and 14-18 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Examiner alleges that claim 1, "consisting of" components (i) and (ii), must exclude the presence of granulating fluid. In view of this interpretation, the Examiner alleges that a composition that does not have granulating fluid is not supported by the application as-filed. Applicant respectfully disagrees for at least the reasons that follow.

First, although the claimed compositions *may* contain a "granulating fluid," its presence in the claimed dosage form is certainly no prerequisite. Paragraph 0010 of the application states, for example, that "the matrix may be tableted by direct compression of the blend of the active ingredients and certain hydrophilic matrix materials". Further, paragraph 0017 specifies that "the drug can be incorporated into fat-wax granulations by spray congealing in air,...,and spray-drying techniques." These methods are known to the ordinary artisan *not* to require the presence of a granulating fluid. Thus, though a granulating fluid may be used in processing certain embodiments of the invention, the application also adequately describes formulations absent same.

Second, claim 1 is directed to a dosage form and its patentability is independent of any method of manufacture *per se*. In the present case, Applicant respectfully notes that granulating fluid is removed in most, if not all, drug manufacturing processes that use same. Hence, even if the claimed composition were *manufactured* with a granulating fluid, the *product* would nevertheless be essentially free of the fluid.

Finally, Applicants respectfully disagree with the Examiner's limiting interpretation of the claims. While claim 1 is directed to a dosage form *consisting of* components (i) and (ii), the homogenous matrix of component (i) *comprises* a mixture of a pharmaceutically active agent and a fat-wax matrix material or particles of a polymeric material selected from a hydrophilic polymer and inert plastic. Hence, though the dosage form itself is limited just to components (i) and (ii), the claims have been drafted to encompass "granulating fluid" by virtue of the "comprising" language for components of the homogenous matrix *per se*.

35 U.S.C. § 112, first paragraph

Claims 3, 14 and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner alleges that claims 3 and 14 "appear to violate the requirement of claim 1 that the sustained release matrix consists of (i) and (ii) because the comprising language of claim 14 opens up the matrix and the layered tablet of claim 3 appears to have matrix components other than (i) and (ii)." Applicants respectfully traverse the rejection.

Claim 3 has been deleted, rendering its rejection moot.

Claim 14 is a "method" claim and use of the transition phrase "comprising" is not necessarily inconsistent with the production of a dosage form "consisting of" components (i) and (ii) of claim 1. Indeed, the language of claim 14 does not expand the *composition* of the dosage form beyond the scope of the composition of claim 1. Again, insofar as language of claim 14 does not allow for the possibility of *components* additional to (i) and (ii), the claim cannot violate the "consisting of" language of claim 1, even though the method "comprise" open-ended *process steps*.

Lastly, claim 15 has been redrafted in light of claim 4 to specify that the mucoadhesive is a "retaining means." Taken together, Applicant respectfully requests withdrawal of the rejections under Section 112.

Claim rejections under 35 U.S.C. § 102

U.S. Patent No. 6,004,582

Claims 1, 3-5, 7 and 14-18 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 6,004,582 to Faour *et al.* ("Faour"). Applicants respectfully traverse this rejection.

Previously, Applicants advanced the position that the claimed invention does not have a semipermeable membrane as taught by Faour. While the Examiner agrees with this premise, the Examiner has interpreted the term "comprising" used in connection with the

"polymeric matrix" to encompass a semipermeable membrane. Applicant respectfully disagrees with this construction of the claims, however, solely in the interest of speeding prosecution of the present case, Applicant has further defined the dosage form to a "homogeneous" matrix, which recitation necessarily precludes the presence of membrane.

U.S. Patent No. 4,713,243

Claims 1, 4-5, 7 and 16-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,713,243 to Schiraldi, *et al.* ("Schiraldi"). Applicants respectfully traverse this rejection.

Schiraldi discloses bioadhesive extruded films "especially useful in *intra-oral* controlled-releasing delivery" of a medicament. Abstract (emphasis added). Other than the mouth, Schiraldi teaches the use of the medicaments for yet other topical locations, such as skin care, gynecological applications, wound care and like. Col. 2, ln. 25-27. In other words, Schiraldi does not disclose a pharmaceutical preparation for a systemic absorption and there is no indication that the discloses preparations are even suitable for such.

The present invention, however, concerns pharmaceutical compositions that *release* an active agent in the oral cavity for substantial *absorption* in the gastrointestinal tract. In other words, the absorption of the drug of the current invention does not happen in the oral cavity as taught by Schiraldi. Rather, the drug is "absorbed solely in the upper GI tract" and "is not absorbed through the oral mucosa to a substantial extent."

U.S. Patent No. 6,197,331

Claims 1, 4-5, 7 and 14-18 are rejected under 35 U.S.C. § 102(b) as being anticipated U.S. Patent No. 6,197,331 to Lerner *et al.* ("Lerner"). Because Lerner teaches the use of "any agent" with the disclosed pharmaceuticals, the Examiner alleges that Lerner also teaches a composition, where in the active ingredient "is not absorbed through the oral mucosa to a substantial extent." Office Action, page 7, item 16. Applicants respectfully traverse this rejection.

Although Lerner states that "any agent can be used" with the disclosed pharmaceutical patches, Applicant respectfully submits that one of ordinary skill in the art would understand

that Lerner teaches the use of "any agent" that can be "absorbed through the oral mucous membrane." Col. 4, para. 3. This qualification on "any agent" is at least apparent from Lerner's characterization of *unsatisfactory* "prior art" preparations, which

> are usually composed of components which are soluble or disintegrable within the mouth. Thus, *the pharmaceutically active agents contained in the preparations are mostly swallowed without being absorbed through the mucous membrane in the oral cavity*. Thus, these preparations are *not completely satisfactory* as a sustained- or controlled-release preparation for the oral cavity." Col. 4, para. 6 (emphasis added).

According to the present invention, however, exactly those agents "unsatisfactory" to Lerner are encompassed: "the active pharmaceutical [ingredient, according to the invention] is one that does not, and is *not* intended to, absorb through the oral mucosa to any appreciable extent." Page 4, paragraph 2 (emphasis added). The claims, as well, have been amended to recite this class of active agents.

Furthermore, Lerner teaches a composition that is prepared as a liquid, wherein the polymers of the matrix are *dissolved*, and then solidified. "An essential feature is a polymer that dissolved in a pharmaceutically acceptable solvent (such as ethanol:water) and that can be plasticized to form a flexible polymer matrix when dried and then inserted in the oral cavity." Col. 8, last para. *See also*, paras. 9 and 12 (teaching *dissolved* polymers). The polymeric materials (*i.e.*, hydrophilic polymer, inert plastic) of the claimed invention, by contrast, are in the form of distinct "particles."[1]

Taken together, Applicant respectfully submits that the claims, currently pending, cannot be anticipated by any of the references of record. Accordingly, withdrawal of the same rejections is respectfully solicited.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date: 16 November 2009 (Monday)

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[1] Should it concern the Examiner, Applicant submits that the maintaining the polymers in "particles", as opposed to in solution, confers release properties unique to the claimed invention.